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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/819,813	03/29/2001	John Kendrup	003300-763	1138

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EXAMINER

PULLIAM, AMY E

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 01/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/819,813

Applicant(s)

KENDRUP ET AL.

Examiner

Amy E Pulliam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 November 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

Receipt of Papers

Receipt is acknowledged of the Amendment B, received by the Office on November 1, 2002.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4, 7, 8, 9, 11, 12, 13, 14, 15, 16, 20, and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 5,639,476 to Oshlack *et al.*.

Applicant is claiming a method for producing a controlled release pharmaceutical preparation comprising preparing a drug containing core, suspending a pore forming agent in an aqueous dispersion of a film forming polymer, coating the solid core with the suspension, and drying the coated substrate.

Oshlack *et al.* disclose a controlled release dosage form, comprising a substrate containing an active agent, said substrate being coated with a plasticized aqueous dispersion consisting essentially of copolymers which are copolymers of acrylic acid and methacrylic acid esters, and a further material which can be a pore-former. Oshlack *et al.* further teach that the coating is applied to the substrate, and the coated substrate is cured at a temperature greater than the glass transition temperature of the aqueous dispersion of said plasticizer water-insoluble

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polymer. See column 36, claim 1. Furthermore, Oshlack *et al.* teach that the controlled release coatings are aqueous dispersions of hydrophobic acrylic polymers. See column 7, lines 35-38. Oshlack *et al.* also teach that the monomers to be used in the polymer coatings may include vinyl esters, such as vinyl acetate and vinyl chloride. See column 7, lines 50-53. Also, the pore former can be selected from a large group, including alkali metal salts, such as potassium chloride. See column 10, line 45 – column 11, line 42. The active agent can be selected from a large list of actives. See column 16, line 42 – column 17, line 44.

Applicant's arguments have been fully considered but are not found to be persuasive.

Applicant argues that the claims recite solid pore formers, and that the pore formers must have a balanced water solubility. Additionally, Applicant argues that the references pore formers can not be suspended in water because they are too water soluble. First, the examiner points to page 4, paragraph 4 of Applicant's response, where Applicant himself admits that Oshlack teaches the use of solid pore formers.

In response to Applicant's argument that Oshlack's pore formers are too soluble, the examiner respectfully disagrees. First, claim 1 does not recite a particular solubility. Claim 1 only contains language regarding balanced water solubility. It is the position of the examiner that this does not require a certain water solubility. Therefore, the rejection over claim 1 is maintained. Furthermore, it is the position of the examiner that many of the pore formers disclosed by Oshlack are, in fact, not very soluble in water, therefore falling within the limitations of Applicant's claims. For example, lithium carbonate has a solubility of 1 g / 78 mL, which equates to 12.82 mg/ 1 mL water. Additionally, starch is practically insoluble in water. Also,

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polyvinyl chloride is soluble in water. (see Merck, numbers 5552, 89524, 7746). Furthermore, Applicant has made the argument as if the solubility required by the claims is less than 50 mg/mL. However, this is not the case, as claim 2 is the only claim requiring a particular solubility, and this claim only requires the solubility be below 100 mg/ mL. There are many pore formers disclosed by Oshlack which have a solubility which meets this standard. Applicant's further discussion that balanced water solubility requires a certain solubility in bodily fluid. The examiner does not find this persuasive because (1) this limitation is not present in the claim language, and (2) the Office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. *See Ex parte Phillips*, 28 U.S.P.Q.2d 1302, 1303 (PTO Bd. Pat. App. & Int. 1993), *Ex parte Gray*, 10 USPQ2d 1922, 1923 (PTO Bd. Pat. App. & Int.) and *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

Applicant also argues that Oshlack *et al.* teach organic solvents, rather than aqueous. The examiner respectfully disagrees and points again to column 7, lines 35-38, where the reference teaches that the controlled release coatings are aqueous dispersions of hydrophobic acrylic polymers.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oshlack *et al.*, as discussed above, and in view of the following comments.

Oshlack *et al.* is described above as teachings applicant's claimed process. Oshlack *et al.* does not specifically teach the claimed particle size for the pore formers. However, it is the position of the examiner that the determination of a particular particle size is within the skill of the ordinary worker as part of the process of normal optimization, and therefore, does not render patentable weight to the claims.

Additionally, Oshlack *et al.* does not specifically teach each of applicant's listed pore formers. However, Oshlack *et al.* does teach the use of pore formers, in general, to create a controlled release composition. Furthermore, it is the position of the examiner that one of ordinary skill in the art would have been motivated to use any pore former in the process taught by Oshlack *et al.*, because Oshlack *et al.* teaches the inclusion of pore formers, in general. The expected result would be a controlled release formulation, where the pore formers act to create channels and pores that fill with the environmental fluid. See column 10, lines 40-44. Therefore, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

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Applicant's arguments have been considered but are not found to be persuasive. Applicant argues many of the same points discussed in the above response to arguments. Applicant further argues that none of the pore formers used in the examples of the reference would work in the instant invention. However, this is not persuasive, because Oshlack teaches many pore formers which do fall within the solubility requirement claimed by Applicant. Additionally, it is not required that Oshlack *et al.* teach the limitations in the examples in order to suggest the limitations of Applicant's claimed invention. Therefore, the rejection is maintained.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E Pulliam whose telephone number is 703-308-4710. The examiner can normally be reached on Mon-Thurs 7:30-5:00, Alternate Fri 8:30-5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

A. Pulliam
Patent Examiner/ AU 1615
January 24, 2003

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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